district court an information against the Amfre Drug Co., Inc., New York, N. Y., and Lewis Stern, president of the corporation, alleging shipment in violation of the Food and Drugs Act, within the period from on or about July 1 to on or about December 27, 1938, from the State of New York into the States of New Jersey, Pennsylvania, Massachusetts, and Rhode Island, of quantities of Causalin which was adulterated and misbranded. The boxes containing a portion of the article were labeled in part: "Aminodimethylpyrazolon-quinolinesulphonate." A circular and a leaflet accompanying one of the shipments bore the statements: (Circular) "Amino-dimethyl-pyrazolon-quinoline-sulphonate * * * The drug used in this study is supplied by Amfre Drug Company under the name of Causalin"; (leaflet) "Amino-dimethyl-pyrazolon-quinoline-sulphonate (Causalin)."

The article was alleged to be adulterated in that its purity fell below the professed standard under which it was sold in that it was represented to consist of aminopyrine (dimethylaminophenyldimethylpyrazolon) and quinolinesulfonate, namely, aminopyrine and quinolinesulfonate; whereas it contained in addition to said drugs a material proportion of salicylic ethyl ester carbonate.

It was alleged to be misbranded in that it consisted of a mixture of aminopyrine (dimethylaminophenyldimethylpyrazolon), salicylic ethyl ester carbonate, and quinolinesulfonate and was offered for sale under the name of another article. "Aminodimethylpyrazolon-Quinolinesulphonate," i. e., aminopyrine and quinolinesulfonate.

Portions of the article were alleged to be misbranded further in that the statements, (boxes of portion) "Aminodimethylpyrazolon-Quinolinesulphonate," and (circular accompanying one shipment) "Chemotherapy: Amino-dimethyl-pyrazolon-quinoline-sulphonate * * * The drug used in this study is supplied by Amfre Drug Company of New York City under the name of Causalin * * * Kimble reports fifty-six cases of chronic nonspecific arthritis were treated with amino-dimethyl-pyrazolon-quinoline-sulphonate (Causalin)," were false and misleading in that the said statements represented that the article consisted of aminopyrine and quinolinesulfonate; whereas it consisted of aminopyrine, salicylic ethyl ester carbonate, and quinolinesulfonate.

The information alleged that the article was also misbranded in violation of the Federal Food, Drug, and Cosmetic Act, as reported in notice of judgment No. 76 published under that act.

On January 30, 1940, the defendants entered pleas of guilty and the court imposed fines for violation of both acts. The fines imposed on the counts charging violation of the Food and Drugs Act amounted to $210 against each defendant.

GROVER B. HILL, *Acting Secretary of Agriculture.*

30997. Misbranding of Enrich Organic Iron Hematinic. U. S. v. Tam Products, Inc., Joseph G. Spitzer, and Marvin Small. Pleas of guilty. Fines, $1,200. (F. & D. No. 42764. Sample Nos. 39901–D, 51200–D.)

The labeling of this product bore false and fraudulent representations regarding its curative and therapeutic effectiveness. It was also labeled to indicate that it contained substantial amounts of organic iron; whereas it contained an insignificant amount of iron, either organic or inorganic.

On November 27, 1939, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Tam Products, Inc., New York, N. Y., and Joseph G. Spitzer and Marvin Small, officers of the corporation, alleging shipment in violation of the Food and Drugs Act as amended, on or about September 28 and November 12, 1938, from the State of New York into the State of Washington, of quantities of Enrich Organic Iron Hematinic that was misbranded.

Analysis of a sample from one of the shipments showed that it consisted essentially of small proportions of an extract of an animal product, compounds of sodium and ammonium, chlorides, sulfates, and phosphates, a trace of an iron compound, glycerin, and water. Biological tests showed that it contained not more than 2 International Units of vitamin B_1 per cc. and not more than 240 Chase-Sherman units of vitamin B_1 per fluid ounce.

The article was alleged to be misbranded in that the statement "Organic Iron Hematinic," borne on the carton and bottle label, was false and misleading in that it represented that the article contained a substantial amount

of organic iron and that when used as directed, it would supply the consumer thereof with therapeutically important doses of organic iron; whereas it did not contain a substantial amount of organic iron and when used as directed, it would not supply the consumer with therapeutically important doses of organic iron since it contained but an inconsequential amount of iron, either organic or inorganic. It was alleged to be misbranded further in that certain statements in the labeling, regarding its curative and therapeutic effects, falsely and fraudulently represented that it was effective as a treatment for iron-poor blood; effective to benefit the nerves and blood, to improve the digestion, to alleviate nervous fatigue, restless sleep, mental depression, irritability, and headaches when associated with secondary anemia and vitamin B_1 deficiency; effective to increase resistance, to help the blood in case of iron-poor anemia, to relieve many nervous symptoms of secondary anemia, to assist in producing a favorable rise in the hemoglobin and red blood cell count, and to insure improvement in appearance and in the state of well-being; effective to be of great benefit to adolescent girls at the onset of menstruation; and effective as a general tonic in convalescence.

On February 15, 1940, pleas of guilty having been entered on behalf of the defendants, the court imposed fines in the total amount of $1,200, i. e., $400 against each defendant.

GROVER B. HILL, *Acting Secretary of Agriculture.*

30998. Adulteration and misbranding of Oralsulin. U. S. v. Lafayette Pharmacal, Inc., and Bern B. Grubb. Pleas of nolo contendere. Corporation fined $50 and costs. Bern B. Grubb fined $25 without costs. (F. & D. No. 42546. Sample Nos. 21735–C, 48552–C, 53661–C.)

The labeling of two of the three shipments of this product bore false and fraudulent statements regarding its curative and therapeutic effectiveness in the treatment of diabetes mellitus; that of a third shipment bore a device conveying the same false and fraudulent implication. The article was also labeled to indicate that it consisted of insulin or an insulin-like substance which was enclosed in a capsule that would resist the action of the gastric juices and protect the product from disintegration in the stomach but which would be dissolved in the intestinal tract; whereas it was not insulin nor did it possess the properties of insulin, its coating was soluble in gastric juices, and the product would dissolve in the stomach. A sample from one shipment was found to contain ginger and that from a second shipment was found to contain starch.

On January 11, 1939, the grand jurors of the United States within and for the Northern District of Indiana presented an indictment against Lafayette Pharmacal, Inc., Lafayette, Ind., and Bern B. Grubb, president of the corporation at the time of the shipments mentioned hereinafter, alleging shipment in violation of the Food and Drugs Act as amended, on or about January 2, January 6, and September 16, 1937, from the State of New York into the States of Louisiana and Maryland, of quantities of Oralsulin which was adulterated and misbranded.

Analyses of the product showed in each instance that it consisted essentially of powdered animal tissues including a small proportion of an enzyme such as is found in pancreas tissue. A sample was found to contain starch and another was found to contain powdered ginger. Biological tests of the samples showed no evidence of insulin activity following oral administration, also that the coating dissolved in the stomach and that the contents disintegrated in the stomach.

The shipment of January 2, 1937, was alleged to be adulterated in that the strength and purity of the article fell below the professed standard and quality under which it was sold in that it was represented to consist of "Enterocap Oralsulin," namely, insulin or an insulin-like substance intended for oral administration, enclosed in a specially devised and perfected capsule which actually protected against gastric action and dissolved in the intestinal canal; whereas it was not insulin, did not contain insulin or any insulin-like substance, it did not possess the properties of insulin, was not enclosed in a capsule which protected it against gastric action and dissolved in the intestinal canal since the capsule was soluble in gastric juice and the said article would disintegrate in the stomach when administered orally. The said shipment was alleged to be misbranded in that the following statements appearing in the labeling, (circular) "In the treatment of Diabetes Mellitus extreme interest was aroused by the introduction of Insulin. As in the case of anything original or novel in therapeutics, many claims were made; and results anticipated have been modified